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| 09/423,715      | 01/12/2000  | CLARE PASSMORE       | 6442/60557          | 7077             |

7590 07/02/2002  
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EXAMINER

BERMAN, ALYSIA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1617

DATE MAILED: 07/02/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/423,715

Applicant(s)

PASSMORE ET AL.

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20, 23 and 25-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20, 23 and 25-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action mailed November 17, 2001, paper no. 10, is persuasive and the finality is withdrawn. The amendment filed May 28, 2002 has been entered. Claims 1, 6, 11-13, 16, 23, 29 and 30 have been amended. Claims 31-37 have been added. Claims 1-20, 23 and 25-37 are pending.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-20, 23 and 25-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific eutectic mixtures disclosed in the examples beginning at page 10, does not reasonably provide enablement for a eutectic mixture of first and second pharmacologically active agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-20, 23 and 25-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1-20, 23 and 25-37 are vague and indefinite because it is unclear what Applicant intends by the phrases, "pharmacologically desirable" and "desirable for transdermal permeation."

7. Claims 9, 31, 34 and 35 are indefinite because it excludes a co-solvent and an additional oil phase. Claims 1 and 23 do not recite a solvent or oil phase. To what solvent and oil phase would these excluded ingredients be in addition?

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. The indicated allowability of claims 10, 23, 28 and 29 is withdrawn in view of the newly discovered reference(s) to US '597, WO '122 and Hawley. Rejections based on the newly cited reference(s) follow.

11. Claims 1-9, 11, 12, 14-20 and 25-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,206,021 (021).

US '021 is directed to oil-in-water emulsions that contain pesticidal substances and can be used for topical application to crops using a spray mixture (title and col. 15, lines 22-27). At column 8, line 65 to column 9, line 13, US '021 discloses that the compositions may be in the form of a eutectic mixture of lipophilic pesticidal substances. The melting point of the eutectic mixture is generally between about  $-20^{\circ}$  and  $30^{\circ}$  C, which is encompassed by the instantly claimed range of less than  $40^{\circ}$  C melting point of the eutectic mixture.

For antifungal agents, antibacterial agents, etc. see column 9, lines 44-64. For arylpropionic acid agents see column 10, lines 1-9. The pharmacologically active agents of claims 28 and 29 are well known in the art. For example, econazole and ketoconazole are well known antifungal agents. It is within the skill in the art to select well-known species from within a disclosed genus expecting similar results. Therefore, no inventive step is seen in using the pharmacologically active agents of instant claims 28 and 29 in the composition of US '021 for their known effects. The reference teaches at column 10, lines 27-29 that an organic solvent may be used but is not necessary.

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Therefore, the reference teaches the limitation of claim 9 excluding a co-solvent or additional oil phase other than the eutectic mixture. However, if an organic solvent is used, the composition of US '021 would then contain an additional pharmaceutically acceptable component as in instant claims 3 and 6.

For gelling or suspension agents, see the thickeners methylcellulose and colloidal silica disclosed at column 14, lines 7-20. US '021 teaches that biopolymers obtained by the fermentation action of *Xanthomonas* bacteria are useful in the compositions as thickeners. It is known in the art that the biopolymer xanthan gum produced by *Xanthomonas* bacteria is commonly used as a thickener. Therefore, US '021 implies the use of xanthan gum in the compositions. For non-ionic surfactants, see column 12, line 47 to column 13, line 49. For other surfactants, see column 13, lines 50-58.

US '021 does not teach the melting point of each of the pharmacologically active and/or pharmaceutically acceptable components. It is within the skill in the art to select optimal parameters of a composition in order to achieve a beneficial effect. Therefore, absent evidence of unexpected results, the melting points of the pharmacologically active and/or pharmaceutically acceptable components do not render the claims patentable over the prior art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '021 using pharmacologically active and/or pharmaceutically acceptable components with optimal melting points with the reasonable expectation of obtaining a stable eutectic emulsion.

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12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,206,021 (021) as applied to claims 1-9, 11, 12, 14-20 and 25-37 above, and further in view of either the USPATFULL abstract of US 5525597 (597) or the CAPLUS abstract of WO 9518122 (122).

US '021 teaches all the limitations of the claims as stated in the 35 U.S.C. 103(a) rejection above. It does not teach the pharmacologically active agents of claim 10.

US '597 teaches that capsaicin enhances the effectiveness of insecticidal compositions. WO '122 teaches that synergistic combinations of insecticides can be obtained with the addition of triclosan.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add either capsaicin or triclosan to the composition of US '021 as taught by either US '597 or WO '122 each expecting to obtain enhanced pesticidal activity.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,206,021 (021) as applied to claims 1-9, 11, 12, 14-20 and 25-37 above, and further in view of The Condensed Chemical Dictionary, 10<sup>th</sup> Ed., Gessner G. Hawley (ed.), Van Nostrand Reinhold Co., New York, (1981), pages 252, 602 and 603.

US '021 teaches all the limitations of the claims as stated in the 35 U.S.C. 103(a) rejection above. It does not teach the pharmaceutically acceptable component of instant claim 13.

Hawley teaches that one of the common uses of lauric acid is as an insecticide (pages 602-603). Hawley also teaches that cinnamic acid is an anthelmintic, a compound that works against helminths (parasitic worms).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '021 and add lauric acid and/or cinnamic acid for their pesticidal effects.

***Response to Arguments***

14. Applicant's arguments filed May 28, 2002 have been fully considered but they are not persuasive.

15. Applicant argues that US '021 fails to teach topical compositions with enhanced transdermal penetration of pharmacologically active agents. Neither preamble use nor inherent properties render a claim to a composition patentable over the prior art composition. *In re Tuominen*, 213 USPQ 89, *In re Pearson*, 181 USPQ 641. Pearson stated that a known composition cannot be patented solely on preamble use. Terms merely setting forth an intended use for, or a property inherent in, an otherwise old composition do not differentiate the claimed composition from those of the prior art. *In re Pearson*, 181 USPQ 641. Difference in use cannot render claimed composition novel. *In re Tuominen*, 213 USPQ 89.

In any event, US '021 is directed to pesticidal compositions that are topically applied to crops. Topical application of the composition to crops would result in topical application to the pests, which would lead to penetration of the pesticides into the pests. Pesticidal compositions are also topically applied to humans for the same purpose.

16. Applicant argues that pesticides are not pharmaceutically acceptable or pharmacologically active. The term pharmaceutically acceptable is interpreted as encompassing any substance that can be used in pharmaceuticals. The term



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pharmacologically active is interpreted as encompassing any substances that have therapeutic activity. The lipophilic substances disclosed by US '021 at column 9, line 25 to column 12, line 40 are encompassed by these definitions. Applicant has not provided any evidence of record that the lipophilic substances of US '021 are not pharmaceutically acceptable or pharmacologically active. With regard to Applicants' statement that pesticides are not drugs, Applicant is referred to definition number (3) of the word, "drug" found in Merriam-Webster's Collegiate Dictionary, 10<sup>th</sup> Ed., Merriam-Webster, Inc., Springfield, MA, (1998), page 355, which states, "a substance other than food intended to affect the structure or function of the body." The pesticides of US '021 are intended to affect the function of the body of the pests at which they are targeted.

17. The instant independent claims are drawn to a composition containing a eutectic mixture of a first pharmacologically active agent and a second pharmacologically active agent and a method of applying the composition to an accessible body part of an animal. US '021 teaches a composition containing a eutectic mixture of various active agents that are encompassed by the phrase, "pharmacologically active agents," that is topically applied to crops ultimately leading to topical application to the animal pests on the crops.

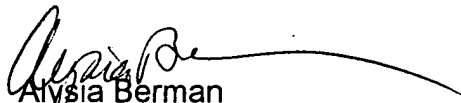
### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

  
Alysia Berman  
Patent Examiner  
June 17, 2002

  
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